

PATENT

In the UNITED STATES PATENT and TRADEMARK OFFICE

APPLICANT: Baxter, et al.	EXAMINER: Not yet assigned
SERIAL NO.: Not yet assigned	ART UNIT: Not yet assigned
FILING DATE: July 18, 2003	DOCKET NO.: 6815.US.D1
TITLE: METHODS AND COMPOSITIONS FOR PROVIDING GLUTAMINE	
<p>I certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Commissioner for Patents, Alexandria, VA 22313-1450 on the date shown below.</p> <p><i>Wendy Detwiler 7-18-03</i></p>	
<p>Wendy Detwiler</p> <p>Date</p>	

Commissioner for Patents
 P. O. Box 1450
 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with their duty of disclosure under 37 C.F.R. §1.56, and as authorized and encouraged under 37 C.F.R. §§ 1.97-1.98 and the provisions of MPEP §§ 609 and 707.05(b), Applicants submit herewith certain patent documents, publications and/or other information ("references") which the Patent and Trademark Office may wish to consider in examining the above-identified patent application. The identification of any reference herein is not intended to be and should not be understood as being an admission that such reference necessarily constitutes "prior art" within the meaning of applicable law.

The cited references are listed on attached form PTO-1449.

- A copy of each cited reference is provided;
- Copies of cited references are not provided because each has previously been made of record in the parent application, or is otherwise known to be in the Examiner's possession.

The Examiner is requested to review and evaluate each cited reference to make an independent assessment of the materiality of each, if any, to the examination of the above-identified application. The Examiner is requested to ignore any underscoring or highlighting which may have been done because such markings may or may not have any relationship to the subject matter of the present invention. The copies being submitted with this Statement are the best copies available at this time. Applicants respectfully request that (1) the references cited herein be made of record; (2) that the Examiner acknowledge his consideration of each reference by initialing and returning the enclosed copy of the PTO-1449 form; and (3) that such references appear on the printed patent as having been considered on the record.

With regard to payment of a fee:

- No fee is due because:
- This Statement is mailed within three months of the filing date of this application, or before the mailing date of a first office action on the merits (see 37 C.F.R. §1.97(b)).
- Applicants certify that each reference cited in this Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement. (see 37 C.F.R. §1.97(e)).
- This Statement is filed after the mailing date of a first Office Action on the merits but before the mailing date of either a final action or a Notice of Allowance (see 37 C.F.R. §1.97(c)) so a fee of **\$180.00** is specified by 37 C.F.R. §1.17(p).

If any fees are owed, or any credit is due pertaining to this case, please charge that fee or apply that credit to Deposit Account No. 01-0025.

Ross Products Division of
ABBOTT LABORATORIES
Dept. 108140-DS/1
625 Cleveland Avenue
Columbus, OHIO 43215-1724

Telephone: (614) 624-3012
Facsimile: (614) 624-3074

Docket : 6815.US.D1

Respectfully submitted,



by Nickki L. Parlet
Reg. No. 44,996

FORM PTO-1449 U.S. Department of Commerce (Rev. 2032) Patent and Trademark Office		Atty. Docket No.: 6815.US.01	Serial No.: 09/973,105
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Baxter, et al.	
(Use several sheets if necessary)		Filing Date: 10/09/01	Group: 1761

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)
	6,221,910	04/24/01	Montner			
	5,462,924	10/31/95	Kihlberg, et al.			
	5,646,118	07/08/97	Kihlberg, et al.			
	5,908,824	06/01/99	Yanagawa			
	5,693,671	12/02/97	Niihara, et al.			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Name	Class	Subclass	Translation (Yes No)
	EP 1 097 646 A2	05/09/01				
	EP 0 547 099 B1	07/30/97				
	WO 92/03155	03/05/92				
	JP 10-101576					

OTHER DOCUMENTS (Including Author , Title, Date, Pertinent Pages, Etc.)

		Brito, et al., "Stable Glutamine Derivatives Reduce Apoptosis in Intestinal Epithelial Cells and Inhibit Cholera Toxin Secretion", American Journal of Tropical Medicine and Hygiene, V. 62 (3 Suppl), 367-368, no. 547
		Patents Abstract of Japan, application number 08260683
		Alitraq® Specialized Elemental Nutrition with Glutamine for Metabolically Stressed Patients with Impaired GI Function, Ross Products Division of Abbott Laboratories
		Optimental® Ready To Feed Elemental, Ross Products Division of Abbott Laboratories
		Sigma-Aldrich Certificate of Analysis, N-Acetyl -L-glutamine, Product Number A9125

EXAMINER

DATE CONSIDERED:

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.: 6815.US.01	Serial No.: 09/973,105
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Baxter, et al.	
(Use several sheets if necessary)		Filing Date: 10/09/01	Group: 1761

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Name	Class	Subclass	Translation (Yes No)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Rothstein, et al., "Chronic Inhibition of Glutamate Uptake Produces a Model of Slow Neurotoxicity", Proc. Natl. Acad. Sci. USA, Vol. 90, pp. 6591-6595, July 1993, Neurobiology
		Caccia, et al., "Pyroglutamate Kinetics and Neurotoxicity Studies in Mice", Toxicology Letters, 16 (1983) 225-229
		McGeer, et al., "Research Note: Neurotoxic Effects of Endogenous Materials: Quinolinic Acid, L-Pyroglutamic Acid, and Thyroid Releasing Hormone (TRH)", Experimental Neurology 86, 410-413 (1984)
		Creer, et al., "Pyroglutamic Acidemia in an Adult Patient", Clinical Chemistry, Vol. 35, No. 4, 1989
		Magnusson, et al., "Utilization of Intravenously Administered N-Acetyl-L-Glutamine in Humans", Metabolism, Vol. 38, No. 8, Suppl 1 (August), 1989: pp. 82-88
		Gouttebel, et al., "Influence of N-Acetylglutamine or Glutamine Infusion on Plasma Amino Acid Concentrations During the Early Phase of Small-Bowel Adaptation in the Dog", Journal of Parenteral and Enteral Nutrition, Vol. 16, No. 2, 1992
		Ollenschläger, et al., "Availability of Glutamine From Peptides and Acetylglutamine for Human Tumor-Cell Cultures", Metabolism, Vol. 38, No. 8, Suppl 1 (August) 1989: pp. 40-42
		Palmerini, et al., "Uptake of Doubly-Labelled N-Acetyl-L-Glutamine in Rat Brain and Intestinal Mucosa <i>In Vivo</i> ", Farmaco[Prat], 1981 July; 36(7): 347-55
		Wallace, et al., "Uptake of Acetylated Peptides from the Small Intestine in Sheep and Their Nutritive Value in Rats", British Journal of Nutrition (1998), 80, 101-108
		Damico, "An Investigation of N-Substituted Methionine Derivatives for Food Supplementation", J. Agr. Food Chem., Vol. 23, No.1, 1975
		Rotruck, et al., "Comparative Metabolism of L-Methionine and N-Acetylated Derivatives of Methionine", The Journal of Nutrition, Vol. 105, No. 3, March 1975
		Boggs, et al., "Acetylmethionine as a Source of Methionine for the Rat", The Journal of Nutrition, Vol. 105, No. 3, March 1975
		Tanabe, et al., "Production of a High-Glutamine Oligopeptide Fraction from Gluten by Enzymatic Treatment and Evaluation of its Nutritional Effect on the Small Intestine of Rats", Journal of Biochemistry 16, (1993), 235-248
		Rooyackers, et al., "Effect on Enterally Administered Glutamine-Rich Protein on the Catabolic Response to a Zymosan Challenge in Rats", Clinical Nutrition (1995) 14: 105-115
		Jiang, et al., "The Impact of Alanyl-Glutamine on Clinical Safety, Nitrogen Balance, Intestinal Permeability, and Clinical Outcome in Postoperative Patients: A Randomized, Double-Blind, Controlled Study of 120 Patients", Journal of Parenteral and Enteral Nutrition, Vol. 23, No. 5, 1999

EXAMINER

DATE CONSIDERED:

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.: 6815.US.01	Serial No.: 09/973,105
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Baxter, et al.	
(Use several sheets if necessary)		Filing Date: 10/09/01	Group: 17161

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Name	Class	Subclass	Translation (Yes No)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		van Zanen, et al., "Parenteral Glutamine Dipeptide Supplementation Does Not Ameliorate Chemotherapy-Induced Toxicity", CANCER, November 15, 1994, Vol. 74, No. 10
		Scheppach, et al., "Effect of Free Glutamine and Alanyl-Glutamine Dipeptide on Mucosal Proliferation of the Human Ileum and Colon", Gastroenterology, 1994; 107: 429-434
		Klassen, et al., "The Pharmacokinetic Responses of Humans to 20 g of Alanyl-Glutamine Dipeptide Differ with the Dosing Protocol but Not with Gastric Acidity or in Patients with Acute Dengue Fever", J. Nutr. 130: 177-182, 2000
		Tenenhaus, et al., "Supplementation of an Elemental Enteral Diet with Alanyl-Glutamine Decreases Bacterial Translocation in Burned Mice", Burns (1994) 20, (3), 220-225
		van der Hulst, et al., "Glutamine and the Preservation of Gut Integrity", The Lancet, Vol. 341: May 29, 1993
		Wirén, et al., "The Effects of a New Amino-Acid Dipeptide Solution on Nitrogen Balance and Humoral Growth Factors in the Postoperative State in Man", Clinical Nutrition, (1995) 14: 97-104
		Decker-Baumann, et al., "Reduction of Chemotherapy-induced Side-effects by Parenteral Glutamine Supplementation in Patients with Metastatic Colorectal Cancer", Eur J Cancer, Vol. 35, No. 2, pp. 202-207, 1999
		Tremel, et al., "Glutamine Dipeptide - Supplemented Parenteral Nutrition Maintains Intestinal Function in the Critically Ill", Gastroenterology, 1994; 107: 1595-1601
		Ziegler, et al., "Safety and Metabolic Effects of L-Glutamine Administration in Humans", Journal of Parenteral and Enteral Nutrition, Vol. 14, No. 4, Supplement, 1990
		Hankard, et al., "Response of Glutamine Metabolism to Exogenous Glutamine in Humans", Am J Physiol 1995 Oct; 269 (4 Pt 1): E663-70
		Anderson, et al., "Oral Glutamine Reduces the Duration and Severity of Stomatitis after Cytotoxic Cancer Chemotherapy", CANCER, October 1, 1998, Vol. 83, No. 7
		Abcouwer, et al., "Is Glutamine a Pretender to the Throne?", Nutrition, Vol. 15, No. 1, 1999
		Saito, et al., "Glutamine as an Immunoenhancing Nutrient", Journal of Parenteral and Enteral Nutrition, Vol. 23, No. 5, 1999
		Wells, et al., "Dietary Glutamine Enhances Cytokine Production by Murine Macrophages", Nutrition, Vol. 15, Nos. 11/12, 1999
		Jones, et al., "Randomized Clinical Outcome Study of Critically Ill Patients Given Glutamine-Supplemented Enteral Nutrition", Nutrition, Vol. 15, No. 2, 1999
		Barbosa, et al., "Pilot Study with a Glutamine-Supplemented Enteral Formula in Critically Ill Infants", Rev. Hosp. Clin. Fac. Med. S.Paulo, 54(1): 21-24, 1999
		Houdijk, et al., "Randomised Trial of Glutamine-Enriched Enteral Nutrition on Infectious Morbidity in Patients with Multiple Trauma", The Lancet, Vol. 352, September 5, 1998
		Long, et al., "Impact of Enteral Feeding of a Glutamine-Supplemented Formula on the Hypoaminoacidemic Response in Trauma Patients", The Journal of Trauma: Injury, Infection, and Critical Care, Vol. 40, No. 1, 1996

EXAMINER

DATE CONSIDERED:

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2032)		U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.: 6815.US.01	Serial No. : 09/973,105
		INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant Baxter, et al.	
		(Use several sheets if necessary)	Filing Date: 10/09/01	Group: 1761

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)
	5,276,018	01/04/94	Wilmore			
	5,288,703	02/22/94	Wilmore			
	5,292,722	03/08/94	Wilmore			
	5,397,803	03/14/95	Smith, et al.			
	RE 35,233	05/07/96	Smith, et al.			
	5,607,975	03/04/97	Smith, et al.			
	5,684,045	11/04/97	Smith, et al.			
	5,763,485	06/09/98	Smith, et al.			
	6,051,270	04/18/00	Monte			
	5,981,590	11/09/99	Panigrahi, et al.			

FOREIGN PATENT DOCUMENTS

Document Number	Date	Name	Class	Subclass	Translation (Yes No)
JP 5236909	09/17/93				
WO 99/49741	10/07/99				
EP 0 665 012 A1	08/02/95				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.: 6815.US.01	Serial No.: 09/973,105
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Baxter, et al.	
(Use several sheets if necessary)		Filing Date: 10/09/01	Group: 1761

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)
	5,561,111	10/01/96	Guerrant, et al.			
	5,039,704	08/13/91	Smith, et al.			
	4,857,555	08/15/89	Smith, et al.			
	5,248,697	09/28/93	Wilmore			

FOREIGN PATENT DOCUMENTS

Document Number	Date	Name	Class	Subclass	Translation (Yes No)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Rouse, et al., "Glutamine Enhances Selectivity of Chemotherapy Through Changes in Glutathione Metabolism", Annals of Surgery, Vol. 221, No. 4, 420- 426, 1995.
		Souba, "Glutamine and Cancer", Annals of Surgery, Vol. 218, No. 6, 715 -728, 1993.
		Acree, et al., "A Kinetic Study of the Cyclization of L-Glutamine to 2-Pyrrolidone-5-carboxylic Acid in a Model System", J. Agric. Food Chem., Vol. 23, No. 4, 1975.
		Airaudo, et al., "A Research Note: Stability of Glutamine and Pyroglutamic Acid under Model System Conditions: Influence of Physical and Technological Factors", Journal of Food Science, Vol. 52, No. 6, 1987.
		Khan, et al., "The stability of L-glutamine in Total Parenteral Nutrition Solutions", Clinical Nutrition (1991) 10: 193- 198
		Gandini, et al., "HPLC Determination of Pyroglutamic Acid as Degradation Product in Parenteral Amino Acid Formulations", Chromatographia, Vol. 36, 1993
		Rieke, et al., "Chronic Intrastriatal L-Pyroglutamate: Neuropathology and Neuron Sparing like Huntington's Disease", Experimental Neurology 104, 147- 154 (1989)
		Rieke, et al., "L-Pyroglutamate: An Alternate Neurotoxin for a Rodent Model of Huntington's Disease", Brain Research Bulletin, Vol. 13, pp. 443-456, 1984
		Chanal, et al., "Brain Penetration of Orally Administered Sodium Pyroglutamate", J. Pharm. Pharmacol. 1988, 40: 584- 585
		Caccia, et al., "Plasma and Brain Levels of Glutamate and Pyroglutamate After Oral Monosodium Glutamate to Rats", Toxicology Letters, 10 (1982) 169- 175
		Ghezzi, et al., "Plasma Pyroglutamic Acid Levels After Oral Administration of Monosodium Glutamate to Human Volunteers", Toxicology Letters, 15 (1983) 123 -129
		de Mello, et al., "Neurochemical Effects of L-Pyroglutamic Acid", Neurochemical Research, Vol. 20, No. 12, 1995, pp. 1437-1441

EXAMINER

DATE CONSIDERED:

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.